No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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TABLE OF CONTENTS

Page

I. Section 1395hh(a)(2) did not require notice-and-comment here 1
II. Section 1395hh(a)(4) did not independently require notice-and-comment rulemaking here 16
III. Respondents' position would substantially undermine the agency's ability to administer the Medicare Program 18

TABLE OF AUTHORITIES

Cases:

Allina Health Servs. v. *Burwell*, No. 16-cv-150 (D.D.C. filed Jan. 29, 2016) 18
Allina Health Servs. v. *Sebelius*, 746 F.3d 1102 (D.C. Cir. 2014) 18
American Hosp. Ass'n v. *Bowen*, 834 F.2d 1037 (D.C. Cir. 1987) 11
Clarian Health West, LLC v. *Hargan*, 878 F.3d 346 (D.C. Cir. 2017) 13
Frederich v. *Secretary of Health & Human Servs.*, 894 F.2d 829 (6th Cir.), cert. denied, 498 U.S. 817 (1990) 7
NLRB v. *Bell Aerospace Co.*, 416 U.S. 267 (1974) 15, 16, 17, 18
Perez v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015) 4, 16
SEC v. *Chenery Corp.*, 332 U.S. 194 (1947) 17
Shalala v. *Guernsey Mem'l Hosp.*, 514 U.S. 87 (1997) 13, 18, 19

Statutes, regulations, and rule: Page

Administrative Procedure Act, 5 U.S.C. 551 *et seq.* 4
5 U.S.C. 553(a)(2) 10
5 U.S.C. 553(b)(3)(A) 16
Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 275-276 3
Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 2037 7
Social Security Act, 42 U.S.C. 301 *et seq.*:
Medicare Act, Tit. XVIII, 42 U.S.C. 1395 *et seq.* 1
Part C, 42 U.S.C. 1395w-21 *et seq.* 3
42 U.S.C. 1395w-21(a)(3) 10, 15
42 U.S.C. 1395w-21(a)(3)(A) 2, 3
Part E, 42 U.S.C. 1395x *et seq.*:
42 U.S.C. 1395y(*l*)(3) 8
42 U.S.C. 1395ff(f)(1)(A) 7
42 U.S.C. 1395hh 4, 9, 12, 14
42 U.S.C. 1395hh(a)(2) ..... *passim*
42 U.S.C. 1395hh(e)(1)(A) 9
42 U.S.C. 1395oo(f)(1) 13
42 U.S.C. 1395ww(d)(5)(F)(i) 1, 3
42 U.S.C. 1395ww(d)(5)(F)(vi)(I) 2, 3, 10, 11
42 C.F.R.:
Section 405.1060(a)(4) 7
Section 405.1835(b)(2)(ii) 12
Section 405.1842 13
Section 405.1842(f)(1)(ii) 14
Section 405.1875(e)(4) 16
Section 412.106(b)(2) 12
Section 412.106(b)(2)(i)(B) 13
Section 412.106(b)(2)(i)(B) (2003) 12
Section 412.106(b)(5) 12

Rule—Continued: Page

Fed. R. Civ. P. 1 advisory committee's note (2007 Amendment) 9

Miscellaneous:

Black's Law Dictionary (10th ed. 2014) 8, 9
51 Fed. Reg. 16,772 (May 6, 1986) 2
H.R. Comm. on Ways and Means, 100th Cong., 1st Sess., *Summary of Conference Agreement on Reconciliation Provisions Within the Jurisdiction of the Committee on Ways and Means* (1987) 10
H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. (1986) 8
H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. (1987) 10, 12

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REPLY BRIEF FOR THE PETITIONER

I. SECTION 1395hh(a)(2) DID NOT REQUIRE NOTICE-AND-COMMENT HERE

A. The Medicare Act, *i.e.*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, in Section 1395hh(a)(2), requires the Department of Health and Human Services (HHS) to promulgate "rule[s], requirement[s], or other statement[s] of policy" through notice-and-comment procedures *only* if they "establish[] or change[]" certain "substantive legal standard[s]." 42 U.S.C. 1395hh(a)(2). The Medicare Act also directs the agency to "provide * * * for an additional payment" each year to hospitals serving a disproportionate share of low-income patients, 42 U.S.C. 1395ww(d)(5)(F)(i), and instructs the agency how to calculate a certain quantity (the "Medicare fraction") used in one step of calculating the amount of that additional payment,

42 U.S.C. 1395ww(d)(5)(F)(vi)(I). That calculation requires the agency to include in the Medicare fraction patient days for patients who are "entitled to benefits under part A." *Ibid.* The underlying question in the parties' dispute is whether patient days for Part C patients, who by definition must be "entitled to benefits under part A," 42 U.S.C. 1395w-21(a)(3)(A), should be included in the Medicare fraction. The Centers for Medicare & Medicaid Services (CMS) instructed the contractors that make the initial determination of the reimbursement amounts hospitals will receive to include Part C patient days in calculating respondents' FY2012 Medicare fractions. But those calculations were not binding on the agency, on courts, or on respondents on subsequent review of the contractors' determinations. The calculation of those fractions thus did not change a substantive legal standard and so were not required by Section 1395hh(a)(2) to be promulgated as regulations using notice-and-comment procedures.

Respondents' brief only confirms that their contrary position has a fatal flaw: if (as respondents say) CMS's interpretation of the Medicare Act embedded in its instructions to its contractors "change[d]" a "substantive legal standard" and was thus required to be promulgated through notice-and-comment procedures, then respondents' alternative interpretation of the Medicare Act, which they say was applied previously by CMS, must have "establishe[d]" a "substantive legal standard" and was therefore likewise required to be promulgated through notice-and-comment procedures. 42 U.S.C. 1395hh(a)(2). And if that were true, the government would be prohibited from adopting respondents' preferred position, too—leaving the agency helpless to

adopt *any* interpretation of the statute without first going through notice-and-comment procedures, and thus unable to fulfill its statutory *duty* to "provide * * * for an additional payment" to respondents and other hospitals. 42 U.S.C. 1395ww(d)(5)(F)(i). That would be absurd. Seeking to avoid the absurdity, respondents claim that the agency had "no reason to engage in * * * notice-and-comment rulemaking" because the agency "had already established the relevant standard, embodied in the 1986 regulation." Resp. Br. 33.

Even the court of appeals did not rely on that reasoning, which is without merit. The 1986 regulation, 51 Fed. Reg. 16,772 (May 6, 1986), could not have addressed the question whether Part C patient days should be included in the Medicare fraction because Part C did not exist in 1986; it was enacted in 1997. Indeed the underlying question of statutory interpretation here is whether "entitled to benefits under part A" in Section 1395w-21(a)(3)(A) (defining the criteria to be a Part C patient) means the same as "entitled to benefits under part A" in Section 1395ww(d)(5)(F)(vi)(I) (defining the Medicare fraction). See Pet. Br. 4. The government maintains that the answer is yes; respondents say it is no. Either way, the interpretive question did not exist before 1997, because Section 1395w-21 did not exist before 1997. See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 275-276 (enacting Section 1395w-21). So the 1986 regulation could not have definitively resolved that question.

Therefore, if respondents are correct that the agency's mere interpretation of the Medicare Act to calculate respondents' FY2012 Medicare fractions somehow "change[d]" a substantive legal standard, then *whichever* way the agency *first* interpreted Section

1395w-21 after its enactment in 1997 would have "establishe[d]" that substantive legal standard. 42 U.S.C. 1395hh(a)(2). And because the agency never promulgated the interpretation of the statute that respondents prefer through notice-and-comment procedures, the court of appeals would have erred in ordering the agency to adopt that reading of the statute. Respondents' position is thus not only incorrect but self-defeating. Under Section 1395hh and the longstanding principles of administrative law embodied in the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, that Section 1395hh(a)(2) was enacted to make applicable to the Medicare program, the agency may adopt interpretations of the Medicare Act without promulgating them through notice-and-comment rulemaking, and may later change its interpretation without undertaking notice-and-comment rulemaking. See *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1207 (2015).

B. As the government's opening brief explains, the calculation of respondents' FY2012 Medicare fractions did not change a "substantive legal standard"—and thus did not need to be promulgated using the notice-and-comment procedures in Section 1395hh—for several reasons, including: (1) the calculation of the fractions is based on a nonbinding interpretation of the Medicare Act that is *at most* an interpretive rule to which the notice-and-comment procedures of Section 1395hh do not apply, Gov't Br. 22-37; (2) the fractions, which are simply one intermediate step in calculating respondents' ultimate reimbursement amounts for the year, do not bind the agency, the hospitals, or the courts, *id.* at 37-41; and (3) at all events the agency here

chose to proceed by adjudication rather than by rulemaking, *id.* at 46-49. Respondents' arguments to the contrary are unavailing.

1. a. The underlying statutory interpretation on which CMS's calculation of respondents' FY2012 Medicare fractions is based is *at most* an interpretive rule, for which subsection (a)(2) does not require notice-and-comment rulemaking. See Gov't Br. 21-29, 37-41. That is because interpretive rules do not carry the force and effect of law. Such rules thus by definition do not establish or change any "substantive legal standard," which is a necessary prerequisite for triggering the notice-and-comment requirement of subsection (a)(2). Respondents counter that subsection (a)(2) contains the term "statement[s] of policy"—a term that as used in the APA refers to statements of how an agency intends to exercise discretionary authority in the future and that also "are not 'binding' either on the agency or on the courts" and do not "carry 'the force of law.'" Resp. Br. 38 (citations omitted; brackets in original). Therefore, respondents conclude, "Congress made clear that Section 1395hh(a)(2) is not limited to agency issuances that carry 'the force and effect of law.'" *Id.* at 39.

But respondents' conclusion elides the critical phrase that follows in subsection (a)(2): "that establishes or changes a substantive legal standard." 42 U.S.C. 1395hh(a)(2). It is true enough that the opening words of subsection (a)(2) include "statement of policy," along with "rule" and "requirement," in identifying the forms a CMS action subject to the notice-and-comment requirement might take. *Ibid.* But subsection (a)(2) then uses limiting language—beginning with the restrictive modifier "that"—to confine the universe of "rule[s], requirement[s], or other statement[s] of policy" subject to

the notice-and-comment requirement to those "that establish[] or change[]" certain "substantive legal standard[s]." *Ibid.* Subsection (a)(2) thus makes clear that the *form* or *label* is immaterial: whether called a "rule," "requirement," or "statement of policy," a given issuance, however styled, must follow the specified notice-and-comment procedures only if it "establishes or changes a substantive legal standard." *Ibid.* That is why subsection (a)(2) does not require notice-and-comment procedures for interpretive rules; even though an interpretive rule may qualify as "rule," such a rule does not "establish[] or change[] a substantive legal standard" and thus falls outside the ambit of subsection (a)(2). *Ibid.*

Respondents' reliance (Resp. Br. 25, 27, 38-39) on the reference in Section 1395hh(a)(2) to a "statement of policy," in isolation, is misplaced in another respect as well. That provision's opening text makes it applicable to a "rule, requirement, or *other* statement of policy" that establishes or changes a substantive legal standard, 42 U.S.C. 13955hh(a)(2) (emphasis added), making clear that "statement of policy" as used in the subsection *includes* a "rule" and "requirement." Thus, subsection (a)(2)'s use of the term "statement of policy" cannot be understood to require notice-and-comment rulemaking for statements that merely explain how the agency intends to exercise its discretion in the future, especially when read together with the succeeding limitation to actions that establish or change a "substantive legal standard." *Ibid.*

b. For similar reasons, respondents' reliance on the express exclusion in subsection (a)(2) of national coverage determinations from the notice-and-comment requirement is misplaced. Resp. Br. 40. Respondents as-

sert that the exclusion is superfluous on the government's reading of subsection (a)(2) because "[a]s instruments 'lacking the force and effect of law,' [national coverage determinations] would have been excluded already." *Ibid.* To be sure, it has been the longstanding position of the government that national coverage determinations do not carry the force and effect of law and thus do not establish or change any substantive legal standard.[1] But that position was challenged in litigation, and at least one district court set aside a pre-1986 national coverage determination for failure to follow the APA's notice-and-comment procedures. See *Friedrich* v. *Secretary of Health & Human Servs.*, 894 F.2d 829, 832-833 (6th Cir.) (describing the district court's holding), cert. denied, 498 U.S. 817 (1990). Although the court of appeals reversed on the ground that the national coverage determination was an interpretive rule, not a legislative rule, *id.* at 837, the case demonstrates that the issue of whether national coverage determinations are legislative rules was a contested issue in the 1980s. It was hardly superfluous for Congress to make clear in 1986 that a national coverage determination "shall not be held unlawful or set aside" for failure to follow notice-and-comment procedures in either the APA or in Section 1395hh, as that had the salutary purpose and effect of eliminating all doubt. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 2037-2038.[2]

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[1] Today, national coverage determinations are generally binding on contractors, administrative law judges, and the Medicare Appeals Council, see 42 C.F.R. 405.1060(a)(4), but not on the Departmental Appeals Board, see 42 U.S.C. 1395ff(f)(1)(A).

[2] As the Conference Report stated, the agency's process for promulgating national coverage determinations, codified today at

c. Respondents also erroneously rely (Pet. App. 13a-14a) on dictionary definitions that distinguish "substantive law" from "procedural law." See Resp. Br. 34-36. In the first place, even the definition respondents embrace supports the government's position, for it describes substantive law as "law that creates, defines, and regulates the rights, duties, and powers of parties." Pet. App. 13a-14a (quoting *Black's Law Dictionary* 1658 (10th ed. 2014)) (internal quotation marks omitted). That definition does not encompass interpretations of existing law, whether in the form of an interpretive rule or agency adjudication. See Gov't Br. 26.

In any event, as the government has explained, a definition based on a distinction between substance and procedure is the wrong definition to use in this context. See Gov't Br. 26-27. The appropriate definition is one distinguishing a substantive (or legislative) *rule* from an interpretive rule. See *id.* at 27-28. Contrary to respondents' suggestion, this is not a distinction that "strays from common meaning." Resp. Br. 35. "Substantive" has many meanings that are equally "common"; the key to understanding the applicable one is context. The context here—a statutory provision dealing with notice-and-comment procedures for an administrative agency—plainly calls for a meaning distinguishing substantive *rules* (which generally require notice-and-comment rulemaking under the APA) from interpretive rules (which do not). *Black's Law Dictionary*

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42 U.S.C. 1395y(*l*)(3), "is designed to assure consultation with the scientific and medical community and the general public," and so "the further procedure of publishing proposed and final regulations in the Federal Register does not seem essential." H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 350-351 (1986).

elsewhere draws that very distinction as well. See Gov't Br. 27-28.

d. Respondents similarly err in relying (Resp. Br. 42) on Section 1395hh(e)(1)(A), which allows retroactive application of a "substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability" under certain circumstances. 42 U.S.C. 1395hh(e)(1)(A). "That the Medicare Act contemplates 'substantive changes' as part of an interpretive rule or statement of policy," respondents say, "strongly supports the conclusion that those instruments can in fact change a 'substantive legal standard' under the Medicare Act." Resp. Br. 42. The conclusion does not follow from the premise, for respondents once again rely on an inapposite meaning of "substantive."

Here, the statute plainly intends to use the definition of "substance" meaning "the essential quality of something, as opposed to its mere form." *Black's Law Dictionary* 1656. After all, alongside "interpretive rules," subsection (e)(1)(A) also lists "manual instructions" and "guidelines of general applicability," 42 U.S.C. 1395hh(e)(1)(A), which do not establish or change a "substantive legal standard," 42 U.S.C. 1395hh(a)(2). This meaning of "substantive" is quite common—even used to describe changes to rules of *procedure*. Fed. R. Civ. P. 1 advisory committee's note (2007 Amendment) ("The style changes to the rules are intended to make no changes in substantive meaning."). Subsection (e)(1)(A) is thus of no assistance to respondents.

e. As the government has explained (Gov't Br. 30-37), the drafting history of Section 1395hh(a)(2) demonstrates that it was enacted to ensure that the Secretary would continue to follow the APA's notice-and-comment

requirements for substantive or legislative rules despite the APA's exception from that requirement for rules concerning "benefits," 5 U.S.C. 553(a)(2). That drafting history also confirms that by limiting the notice-and-comment requirement to actions that "establish[] or change[]" certain "substantive legal standard[s]," Congress expressly excluded the agency's nonbinding interpretations of the Medicare Act. Gov't Br. 30-37. Respondents note that the "initial House bill" required notice-and-comment rulemaking for actions that have a "significant effect on * * * the payment for services," and contend that the final enacted legislation means the same thing. Resp. Br. 44 (quoting H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 563 (1987) (1987 Conf. Report)). But had Congress wanted to implement the House bill, it would have simply enacted it as it was worded; that the conference committee *changed* the language to "establishes or changes a substantive legal standard" strongly suggests that the enacted bill means something different from the House bill.[3]

Indeed, the government's opening brief explains (at 34, 36-37) that the committee changed the language to "reflect[] recent court rulings." 1987 Conf. Report 566. Such rulings could only have been in cases under the

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[3] Respondents also cite (Resp. Br. 44) a December 22, 1987 summary from the House Ways and Means Committee, but that generally worded summary did not address the specific question here, and it postdated both the conference committee's report and the final legislation's passage by the House and the Senate, making it of questionable interpretive value in any event. Indeed the summary expressly says it "should not be construed as an official record reflecting the conference agreement." H.R. Comm. on Ways and Means, 100th Cong., 1st Sess., *Summary of Conference Agreement on Reconciliation Provisions Within the Jurisdiction of the Committee on Ways and Means*, at III.

APA, and they included the then-recent ruling in *American Hospital Association* v. *Bowen*, 834 F.2d 1037 (D.C. Cir. 1987). *American Hospital Association* reiterated that the APA's notice-and-comment requirement applies only to "*substantive* rules" that "create *law*" and "establish[] a *standard* of conduct which has the force of law," *id.* at 1045-1046 (emphases added; citations omitted)—language plainly echoed in the text of Section 1395hh(a)(2) that the conference committee adopted and Congress enacted. True, as respondents point out (Resp. Br. 35), *American Hospital Association* also stated that *procedural* rules need not be promulgated through notice-and-comment rulemaking either. 834 F.2d at 1050-1051. But that statement does not mean that all non-procedural rules must go through notice and comment. Rather, the court was merely emphasizing that a rule must be *both* non-interpretive *and* non-procedural to trigger the APA's notice-and-comment requirement. *Id.* at 1046, 1051.

The key point is that Congress enacted Section 1395hh for one specific purpose: to require HHS to comply with *the APA* in promulgating certain regulations regarding payment for services. See Gov't Br. 35-37. Congress did that by incorporating APA standards into the Medicare Act. See *ibid.* Nothing in the drafting history of the 1986 or 1987 amendments to Section 1395hh suggests that Congress intended to import anything other than ordinary and longstanding administrative law principles into the Medicare Act. Under those principles, an agency's nonbinding interpretation of the statute it administers (*i.e.*, an interpretive rule) does not, by definition, establish or change any substantive legal standard. Respondents neither contest this simple point nor explain why, if Congress had wanted to

deviate significantly from these principles, it would have done so by incorporating language from "recent court rulings" *interpreting the APA* into Section 1395hh and rejecting the broader language in the House proposal. 1987 Conf. Report 566.

2. a. Respondents do not meaningfully defend the court of appeals' reasoning that the FY2012 Medicare fractions calculated and posted on CMS's website are "binding" in a sense that would require notice-and-comment rulemaking simply because the agency's own private contractors must adhere to them in making payment determinations. Cf. Pet. App. 12a-13a. Rather, respondents repeatedly insist that the FY2012 Medicare fractions are binding on hospitals. *E.g.*, Resp. Br. 9, 26, 28-30, 38 & n.12, 57. Specifically, respondents claim that "the fractions and the policy embedded in them are binding on all hospitals nationwide * * * in filing Medicare cost reports." *Id.* at 57. But hospitals remain free to challenge not only the calculated fractions, but also the ultimate reimbursement determinations that are made using those fractions, in administrative proceedings and, eventually, in court. See 42 C.F.R. 405.1835(b)(2)(ii). Indeed that is precisely what respondents did here.

The authority respondents cite (Resp. Br. 9, 57) for their contrary position, 42 C.F.R. 412.106(b)(2) and (5), simply begs the question—for that is the regulation defining the Medicare fraction in the first instance. See generally Gov't Br. App. 19a-27a (reproducing the 2003, 2004, and current versions of the regulation). The version applicable to this dispute says simply that the Medicare fraction includes in the numerator patient days for patients "entitled to both Medicare Part A and SSI," 42 C.F.R. 412.106(b)(2)(i)(B) (2003) (reproduced at

Gov't Br. App. 20a), which does not answer the question whether Part C patients days count.[4] As a result, absent a final judgment in an adjudication, the agency's inclusion of Part C patient days in respondents' FY2012 Medicare fractions is itself not binding on anyone but the agency's own contractors.

Therefore, neither the FY2012 fractions nor the statutory interpretation on which they are based is binding in the relevant sense—not on hospitals, not on the agency, and not on courts. As with all instructions to its own contractors—such as the Provider Reimbursement Manual provision the Court held was an interpretive rule in *Shalala* v. *Guernsey Memorial Hospital*, 514 U.S. 87, 97, 99-100 (1997)—the agency's computation of respondents' FY2012 Medicare fractions "bind neither CMS nor the Board in adjudications," "do not change the legal standards that govern the hospitals," and "do not change the legal standards that govern the agency." *Clarian Health West, LLC* v. *Hargan*, 878 F.3d 346, 355-356 (D.C. Cir. 2017).

b. Respondents briefly assert (Resp. Br. 29) that CMS's publication of their FY2012 Medicare fractions must have been binding on the agency because respondents successfully obtained expedited judicial review, which is available if "the Board determines * * * that it is without authority to decide" a "question of law or regulations." 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1842. Respondents misapprehend the reason *why* they were able to obtain expedited judicial review. It was not because the Provider Reimbursement Review Board thought itself bound by the FY2012 fractions.

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[4] The current version makes clear that "entitled to * * * Medicare Part A" "includ[es] Medicare Advantage (Part C)" patient days. 42 C.F.R. 412.106(b)(2)(i)(B) (reproduced at Gov't Br. App. 25a).

See Pet. App. 71a-73a. Rather, the Board allowed expedited judicial review because respondents *framed* their case as a "challenge" to the "procedural validity of" a purported "regulation" issued by CMS following the remand in the previous *Allina* case. 42 C.F.R. 405.1842(f)(1)(ii); see Pet. App. 70a-71a. The court of appeals agreed, but held that the Board's decision was not reviewable. Pet. App. 10a-11a. But of course the very dispute here is whether respondents' FY2012 Medicare fractions, or the underlying statutory interpretation on which the fractions were based, must be promulgated as a "regulation" under Section 1395hh in the first place. 42 U.S.C. 1395hh(a)(2). To bootstrap respondents' own framing of their challenge into a legal conclusion about the binding nature *vel non* of CMS's instructions to its own contractors would be entirely circular.

3. At all events, the government's opening brief explains (at 46-49) that Section 1395hh does not apply at all when the agency chooses to proceed via case-by-case adjudication rather than by rulemaking. Respondents assert that this case involves the agency's attempt to fill a "statutory gap," and thus *must* be accomplished by promulgating a regulation. Resp. Br. 36 (citation omitted). As discussed earlier, this assertion only underscores the incorrectness of respondents' argument: if there is indeed a statutory gap, and if (as respondents maintain) it can be filled only through notice-and-comment rulemaking, then the agency would have had to undertake notice-and-comment rulemaking even to adopt *respondents'* preferred interpretation of the statute, for that would fill the purported gap no less than the government's interpretation of the statute.

Regardless, an agency always remains free to choose whether to fill a statutory or interpretive gap by rulemaking or by adjudication. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). Nothing in the text of Section 1395hh(a)(2) displaces that fundamental principle of administrative law; to the contrary, subsection (a)(2) applies only to "rule[s]", "regulation[s]" and "other statement[s] of policy"—not to adjudications.

Here, after the D.C. Circuit vacated the 2004 regulation in a 2014 decision, see Gov't Br. 9, 47-48, the agency had little choice but to fill the alleged "gap" for fiscal years between 2004 and 2014 through case-by-case adjudication. In doing so, the agency interpreted the statutory text and concluded that "entitled to benefits under part A" in 42 U.S.C. 1395w-21(a)(3) has the same meaning as "entitled to benefits under part A" in 42 U.S.C. 1395ww(d)(5)(F)(i)(I) does. That the agency's attempt to adopt this legal position by regulation failed did not in any way deprive it of the power to adopt this legal position by adjudication. *Bell Aerospace*, 416 U.S. at 292.

Respondents also argue that it begs the question to say that an agency action lacking "the force and effect of law" need not be promulgated through notice-and-comment procedures because it is the notice-and-comment procedures themselves that give the action such force and effect. Resp. Br. 37-38 (citation omitted). But an agency can *choose* to promulgate through notice-and-comment rulemaking a statutory interpretation that it could otherwise issue in another form, such as by inclusion in the Provider Reimbursement Manual, that does not require notice and comment. Moreover, if respondents' contention were true, it would also be true of the APA, which exempts from its notice-and-comment

requirements interpretive rules and statements of policy, which by definition do not have the force and effect of law. See 5 U.S.C. 553(b)(3)(A); *Mortgage Bankers Assn.*, 135 S. Ct. at 1208. Regardless, as described above, agencies are entitled to adopt a legal position through case-by-case adjudication rather than by regulation, *Bell Aerospace*, 416 U.S. at 294, and, as under the APA, a final adjudicative decision by the Secretary (which we do not have here because respondents short-circuited the administrative review process) would bind the parties—all of whom would have had the chance to be heard. See 42 C.F.R. 405.1875(e)(4). Section 1395hh(a)(2) does not displace this fundamental principle of administrative law either.

II. SECTION 1395hh(a)(4) DID NOT INDEPENDENTLY REQUIRE NOTICE-AND-COMMENT RULEMAKING HERE

If subsection (a)(2) did not require the agency to engage in notice-and-comment rulemaking here, subsection (a)(4) does not provide an independent basis to conclude otherwise. See Gov't Br. 44-46. That is because subsection (a)(4) applies only to a "regulation" promulgated through notice-and-comment procedures in the first instance. See *ibid.* Therefore, if CMS's publication of respondents' FY2012 fractions changed a relevant substantive legal standard, then subsection (a)(2) is sufficient for respondents to prevail; it is unnecessary to rely on subsection (a)(4). If, on the other hand, CMS's publication of the FY2012 fractions did *not* change a relevant substantive legal standard, then that action was not subject to the Medicare Act's notice-and-comment requirements at all—not the one in subsection (a)(2), and not the one in subsection (a)(4). Contrary to re-

spondents' assertion (Resp. Br. 51), that does not render subsection (a)(4) "window dressing." Rather, subsection (a)(4) simply provides an *additional* requirement for regulations promulgated through notice-and-comment procedures. Here, however, the challenged agency action is not the promulgation or enforcement of a "regulation" in the first instance.

Respondents also assert that subsection (a)(4) applies because the government is attempting to give "effect" to the vacated 2004 regulation. Resp. Br. 49-50. Not so. CMS, in publishing respondents' FY2012 fractions, did not give effect to the regulation; it gave effect to the Medicare Act as it understood the Act—specifically, the statutory provision defining the Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). As the district court unequivocally found, "[respondents'] posted 2012 SSI fractions were not calculated in reliance on the vacated rule." Pet. App. 105a. Instead, the agency "appropriately relied on and interpreted the underlying [Medicare] statute to calculate" the FY2012 fractions. *Id.* at 31a.

Finally, respondents assert that even when an agency chooses to proceed through adjudication, it cannot achieve the same "result" as giving effect to a regulation that would violate the logical-outgrowth requirement of subsection (a)(4). Resp. Br. 52. That is incorrect, and respondents do not cite any authority to support that assertion. Rulemaking and adjudication are *alternative* means for an agency to carry out its functions. *Bell Aerospace*, 416 U.S. at 294; *SEC* v. *Chenery Corp.*, 332 U.S. 194, 201 (1947). Rulemaking has certain advantages, see Gov't Br. 47, but a rulemaking that is ineffective on procedural grounds does not forever tarnish the legal position set forth in the pro-

posed rule. The agency remains free to adopt the position through case-by-case adjudication. That is what the agency did in the earlier *Allina* litigation after the 2004 rule had been vacated. See Gov't Br. 9; *Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014); see also *Allina Health Servs.* v. *Burwell*, No. 16-cv-150 (D.D.C. filed Jan. 29, 2016) (challenging the decision of the CMS Administrator on remand). Indeed, this Court made clear in *Bell Aerospace* that an agency could employ case-by-case adjudication to set forth its position *even if* that position "previously had been spelled out in a general rule or regulation." 416 U.S. at 292 (citation omitted). Respondents do not even cite, much less address, *Bell Aerospace* and the bedrock rule of administrative law that it reiterates.

III. RESPONDENTS' POSITION WOULD SUBSTANTIALLY UNDERMINE THE AGENCY'S ABILITY TO ADMINISTER THE MEDICARE PROGRAM

As the government has explained, respondents' theory, if adopted, has the potential to substantially undermine effective administration of the Medicare program, not least because its rationale would encompass not just the Medicare fractions at issue here but nearly every instruction to the agency's contractors, including those contained in the Provider Reimbursement Manual. Gov't Br. 41-43. That would run afoul of this Court's holding in *Guernsey*, which held that interpretive rules predating the 1986 amendments to Section 1395hh, including the Provider Reimbursement Manual provision at issue in that case, need not go through the APA's notice-and-comment procedures. 514 U.S. at 98-99.

Respondents do not meaningfully respond to this concern, distinguishing *Guernsey* solely on the basis that it was "decided under the APA," Resp. Br. 29 n.6,

without explaining either how their theory here would not undermine *Guernsey* or why Section 1395hh(a)(2) should be construed to do so, given that Congress chose to incorporate APA rulemaking principles into the Medicare Act. Indeed *Guernsey* recognized that issuing interpretive rules and guidance to contractors that do not bind the agency or courts can be "a sensible structure for the complex Medicare reimbursement process." 514 U.S. at 101. Respondents' reassurance that not *all* contractor instructions "concern 'the payment for services, or the eligibility or individuals, entities, or organizations to furnish or receive services or benefits,'" Resp. Br. 57 & n.15 (citation omitted), rings hollow, for a significant number of contractor instructions (including much of the Provider Reimbursement Manual) *do* concern those areas. Respondents' theory, if accepted, would appear to subject all of those to notice-and-comment rulemaking requirements. That would substantially undermine the agency's ability to administer the broad and complex Medicare program, in contravention of the plain text of Section 1395hh limiting the notice-and-comment requirement to issuances that establish or change a "substantive legal standard." Nothing in Section 1395hh suggests that Congress intended to impose such drastic constraints on CMS.

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For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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Solicitor General

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